Operator and Service Manual

POWERHEART® AED G3 Plus

CARDIAC SCIENCE

AT THE HEART OF SAVING LIVES™

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PATENTS

This device is covered by the following U.S. and foreign patents:

5,792,190; 5,999,493; 5,402,884; 5,579,919; 5,749,902; 5,645,571; 6,029,085; 5,984,102; 5,919,212; 5,891,172; 5,674,266; 5,700,281; 5,891,173; 5,968,080; 6,263,239; 5,797,969; D402,758; D405,754; 5,909,138; 6,173,203; 6,088,616; 5,897,576; 5,955,956; 6,083,246; 6,064,909; 6,038,473; 5,868,794; 6,115,638; 6,366,809; 5,474,574; 6,246,907; 6,289,243; 6,411,846; 6,480,734; 6,658,290; EP00756878

Other U.S. and foreign patents pending.

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Limited Warranty

Limited Warranty Cardiac Science Corporation ("Cardiac Science") warrants to the original purchaser that its AEDs and stated battery operating life will be free of any defect in material and workmanship according to the terms and conditions of this Limited Warranty ("Limited Warranty"). For purposes of this Limited Warranty, the original purchaser is deemed to be the original end user of the product purchased. This Limited Warranty is NONTRANSFERABLE and UNASSIGNABLE.

For How Long? This Limited Warranty covers the following products or parts for the following time periods:

- Seven (7) years from the date of the original shipment to the original purchaser for Powerheart AED automated external defibrillators with AED battery P/N (9146). Warranty duration for the pads, batteries and accessories are covered below.
- Disposable defibrillation pads shall be warranted until the expiration date.
- Lithium batteries P/N (9146) have a full operational replacement warranty of four (4) years from the date of installation into a Powerheart AED.
- One (1) year from the date of original shipment to the original purchaser for Powerheart AED accessories. The terms of the Limited Warranty in effect as of the date of original purchase will apply to any warranty claims.

What You Must Do: Please complete and submit the Warranty Validation Form within 30 days of original shipment. You will find the Warranty Validation Form enclosed in your original package, or you can fill it out and submit it online at http://www.cardiacscience.com/products/aed_warranty.cfm. Or, complete and mail the warranty validation card enclosed in your original package.

To obtain warranty service for your product, call us toll free at 888.466.8686 seven days a week, 24 hours a day. Our customer service representative will try to resolve your issue over the phone. If necessary, and at our sole discretion, we will arrange for service or a replacement of our product.

What We Will Do: If your Cardiac Science product is returned within 30 days of the date it was purchased, at the direction of a customer service representative, we will repair or replace it with a new product of equal value at no charge to you or offer a full refund of the purchase price, provided the warranty applies. Cardiac Science retains the exclusive right to repair or replace the product or offer a full refund of the purchase price at its sold discretion. SUCH REMEDY SHALL BE YOUR SOLE AND EXCLUSIVE REMEDY FOR ANY BREACH OF WARRANTY.

If your Cardiac Science product is returned, at the direction of a customer service representative, after 30 days but within the warranty period, Cardiac Science, at its sole discretion, will repair your product or replace it. The repaired or replacement product will be warranted subject to the terms and conditions of this Limited Warranty for either (a) 90 days or (b) the remainder of the original warranty period, whichever is longer, provided the warranty applies and the warranty period has not expired.

Obligations and Warranty Limits

Limited Warranty Obligation: Exclusive Remedy

THE FOREGOING LIMITED WARRANTY IS IN LIEU OF AND SPECIFICALLY EXCLUDES AND REPLACES ALL OTHER EXPRESSED OR IMPLIED WARRANTIES INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

Some states do not allow limitations on how long an implied warranty lasts, so this limitation may not apply to you.

NO PERSON (INCLUDING ANY AGENT, DEALER, OR REPRESENTATIVE OF CARDIAC SCIENCE) IS AUTHORIZED TO MAKE ANY REPRESENTATION OR WARRANTY CONCERNING CARDIAC SCIENCE PRODUCTS, EXCEPT TO REFER PURCHASERS TO THIS LIMITED WARRANTY.

YOUR EXCLUSIVE REMEDY WITH RESPECT TO ANY AND ALL LOSSES OR DAMAGES RESULTING FROM ANY CAUSE WHATSOEVER SHALL BE AS SPECIFIED ABOVE. CARDIAC SCIENCE SHALL IN NO EVENT BE LIABLE FOR ANY SPECIAL, PUNITIVE, INDIRECT, CONSEQUENTIAL OR INCIDENTAL DAMAGES OF ANY KIND, INCLUDING, BUT NOT LIMITED TO, EXEMPLARY DAMAGES,

COMMERCIAL LOSS FROM ANY CAUSE, BUSINESS INTERRUPTION OF ANY NATURE, LOSS OF PROFITS OR PERSONAL INJURY OR DEATH, EVEN IF CARDIAC SCIENCE HAS BEEN ADVISED OF THE POSSIBILITIES OF SUCH DAMAGES, HOWEVER OCCASIONED, WHETHER BY NEGLIGENCE OR OTHERWISE.

Some states do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

What This Warranty Does Not Cover: This Limited Warranty does not cover defects or damages of any sort resulting from, but not limited to, accidents, damage while in transit to our service location, product tampering, unauthorized product alterations, unauthorized service, unauthorized product case opening, failure to follow instructions, improper use, abuse, neglect, fire, flood, war or acts of God. Cardiac Science makes no warranty claim as to the compatibility of Cardiac Science products with any non-Cardiac Science products, parts or accessories.

This Limited Warranty is Void if:

- Any Cardiac Science product is serviced or repaired by any person or entity other than Cardiac Science unless specifically authorized by Cardiac Science.
- Any Cardiac Science product case is opened by unauthorized personnel or if a product is used for an unauthorized purpose.
- Any Cardiac Science product is used in conjunction with incompatible products, parts or accessories, including but not limited to batteries. Products, parts and accessories are not compatible if they are not Cardiac Science products intended for use with the Powerheart AED.

If The Warranty Period has Expired: If your Cardiac Science product is not covered by our Limited Warranty, call us toll free at 888.466.8686 for advice as to whether we can repair your Powerheart AED, and for other repair information, including charges. Charges for non-warranty repairs will be assessed and are your responsibility. Upon completion of the repair, the terms and conditions of this Limited Warranty shall apply to such repair or replacement product for a period of 90 days.

This warranty gives you specific legal rights, and you may also have other rights, which vary from state to state.

1 Product Information and Safety

What's in this chapter

- Contact Information
- Product Models
- Product References
- Safety Terms and Definitions
- Safety Alert Descriptions
- Symbol Descriptions

Before Operating the Powerheart G3 AED:

Become familiar with the various safety alerts in this section.

Safety alerts identify potential hazards using symbols and words to explain what could potentially harm you, the patient, or the Powerheart G3 AED.

Contact Information

To order additional Powerheart G3 AEDs or accessories worldwide:

- Toll Free (USA and Canada): +1.800.991.5465
- Telephone: +1.425.402.2690
- Fax: +1.425.402.2001
- Email: customerservice@cardiacscience.com

To receive 24-hour customer support:

There is no charge to the customer for a customer support call. Please have the serial and model numbers available when contacting Customer Service. (The serial and model numbers are located on the underside of the AED.)

- Toll Free (USA and Canada): +1.888.466.8686
- Telephone: +1.425.402.2691

- Email: techsupport@cardiacscience.com
- Website: www.cardiacscience.com

Defibrillator Tracking

Defibrillator manufacturers and distributors are required, under the Safe Medical Devices Act of 1990, to track the location of defibrillators they sell. Please notify Cardiac Science Customer Service in the event that your defibrillator is sold, donated, lost, stolen, exported, destroyed or if it was not purchased directly from Cardiac Science or an authorized dealer.

Product Models

This manual is for Powerheart G3 Plus model 9390E and Powerheart G3 Plus Automatic 9390A AED models. They share a basic set of features and differences are noted throughout the manual.

Product References

For purposes of retaining simple, clear instructions in this manual, note the product references used. Features, specifications, operating instructions and maintenance common to product models will be referred to as:

"Powerheart G3 AED", "AED", or "device" refers to both Powerheart G3 model 9390E and Powerheart G3 Automatic model 9390A AEDs unless otherwise noted.

Warranty Information

The Powerheart G3 AED Operation and Service Manual and any and all information contained herein (except for the *Limited Warranty* chapter) do not constitute any warranty as to the Powerheart G3, Powerheart G3 Automatic or any related products in any manner whatsoever. The *Limited Warranty* chapter in this manual serves as the sole and exclusive warranty provided by Cardiac Science regarding Powerheart G3 AED products.

Safety Terms and Definitions

The symbols shown below identify potential hazard categories. The definition of each category is as follows:

DANGER

This alert identifies hazards that will cause serious personal injury or death.

WARNING

This alert identifies hazards that may cause serious personal injury or death.

CAUTION

This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

Safety Alert Descriptions

The following is a list of Powerheart G3 AED safety alerts that appear in this section and throughout this manual.

Read and understand these safety alerts before operating the AED.

DANGER: Fire and Explosion Hazard

Do not use in the presence of flammable gasses (including concentrated oxygen) to avoid possible explosion or fire hazard.

WARNING: Shock Hazard

Defibrillation shock current flowing through unwanted pathways is potentially a serious electrical shock hazard. To avoid this hazard during defibrillation abide by all of the following:

- Do not use in standing water or rain. Move patient to dry area
- Do not touch the patient, unless performance of CPR is indicated
- Do not touch metal objects in contact with the patient
- Keep defibrillation pads clear of other pads or metal parts in contact with patient
- Disconnect all non-defibrillator proof equipment from the patient before defibrillation

WARNING: Shock and Possible Equipment Damage.

Disconnect all non-defibrillator proof equipment from the patient before defibrillation to prevent electrical shock and potential damage to the equipment.

WARNING: Electric Shock and Fire Hazard.

Do not connect any telephones or unauthorized connectors to the socket on this equipment.

WARNING: Battery is Not Rechargeable.

Do not attempt to recharge the battery. Any attempt to recharge the battery may result in an explosion or fire hazard.

WARNING: Shock Hazard.

Do not disassemble the AED. Failure to observe this warning can result in personal injury or death. Refer maintenance issues to Cardiac Science authorized service personnel.

WARNING: Possible Radio Frequency (RF) Susceptibility.

RF susceptibility from cellular phones, CB radios, and FM 2-way radio may cause incorrect rhythm recognition and subsequent shock advisory. When attempting a rescue using the AED, do not operate wireless radiotelephones within 1 meter of the AED – turn power OFF to the radiotelephone and other like equipment near the incident.

WARNING: Possible Interference with Implanted Pacemaker.

Therapy should not be delayed for patients with implanted pacemakers and a defibrillation attempt should be made if the patient is unconscious and not breathing. The AED has pacemaker detection and rejection, however with some pacemakers the AED may not advise a defibrillation shock. (Cummins, R., ed., Advanced Cardiac Life Support; AHA (1994): Ch. 4)

When placing Pads:

- Do not place the pads directly over an implanted device.
- Place the pad at least one inch from any implanted device.

WARNING: Electromagnetic Compatibility.

Use of accessories or cables other than those specified, with the exception of accessories and cables sold by Cardiac Science Corporation as replacement parts for internal components, may result in increased emissions or decreased immunity of the AED.

WARNING: Improper Equipment Placement.

Position the AED away from other equipment. If it is necessary to use the AED adjacent to or stacked with other equipment, then observe the AED to verify normal operations.

CAUTION: Restricted Use.

Federal law restricts this device to be sold by or on the order of a physician or practitioner licensed by state law in which he/she practices to use or order the use of the device.

CAUTION: Read this Operation and Service Manual carefully.

It contains information about your safety and the safety of others. Become familiar with the controls and how to use the AED properly before operating the product.

CAUTION: Temperature Extremes.

Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The RescueReady® daily self-test verifies the impact of extreme environmental conditions on the AED. If the daily self-test determines environmental conditions outside of the AED's operating parameters, a "Service Required" alert will be issued to prompt the user to move the AED to environmental conditions within the acceptable operating parameters at once. See Chapter 7, *Technical Data*.

CAUTION: Lithium Sulfur Dioxide Battery.

Pressurized contents: never recharge, short circuit, puncture, deform, or expose to temperatures above 65°C (149°F). Remove the battery when discharged.

CAUTION: Battery Disposal.

Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

CAUTION: Use only Cardiac Science Approved Equipment.

Using batteries, pads, cables, or optional equipment other than those approved by Cardiac Science may cause the AED to function improperly during a rescue.

CAUTION: Possible Improper AED Performance.

Using pads that are damaged or expired may result in improper AED performance.

CAUTION: Serial Communication Cable.

The AED will not function during a rescue when the serial communication cable is connected to its serial port. When the serial communication cable is connected to the AED during a rescue, the prompt "Remove Cable to Continue Rescue" will be heard until you remove the serial communication cable.

CAUTION: Moving the Patient During a Rescue.

During a rescue attempt, excessive jostling or moving of the patient may cause AEDs to improperly analyze the patient's cardiac rhythm. Stop all motion or vibration before attempting a rescue.

CAUTION: Serial Communication Cable.

The serial communication cable is only for use with the AED; it is not to be used with a telephone.

CAUTION: Systems Statement.

Equipment connected to the analog and digital interfaces must be certified to the respective IEC standards (i.e. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment).

Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Anybody who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore, responsible that the system complies with the requirements of the system standard IEC 60601-1-1.

CAUTION: Case Cleaning Solutions.

When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or a glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

CAUTION: Equipment Malfunction.

Portable and RF communications equipment may affect the AED. Always observe the recommended separation distances as defined in the EMC declaration tables.

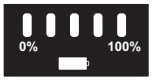
CAUTION: Equipment Malfunction.

The AED requires special precautions regarding EMC. Use the AED according to the guidelines of the EMC declaration tables.

Symbol Descriptions

The following symbols may appear in this manual, on the AED, or on its optional components. Some of the symbols represent standards and compliances associated with the AED and its use.

Symbol	Description
	Caution. Consult accompanying documentation.
	Dangerous Voltage: The defibrillator output has high voltage and can present a shock hazard. Please read and understand all safety alerts in this manual before attempting to operate the AED.
	Defibrillator Proof Type BF Equipment: The AED, when connected to the patient's chest by the pads, can withstand the effects of an externally applied defibrillation shock.
CE 0086	CE Mark: This equipment conforms to essential requirements of the Medical Device Directive 93/42/EEC.
IP24	The AED is protected against the effects of splashing water in accordance with IEC 60529.
	Classified by ETL Semko with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, EN60601-1 and EN60601-2-4.Conforms to UL Standard UL60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.
	International symbol for ON. Open the lid to turn on the AED.

Symbol	Description
	Indicates the AED battery status. The illuminated areas indicate the remaining battery capacity.
	Check pads. The pads are missing, not connected or have compromised functionality.
	Indicates AED requires maintenance by authorized service personnel.
	When the SHOCK indicator is lit, press this button to deliver a defibrillation shock.
	A red indicator with a BLACK X means the AED requires operator attention or maintenance, and is not RescueReady.
	A green indicator without a BLACK X means the AED is RescueReady.
	Use pads by this date.
	Date of manufacture, year and month.

Symbol	Description
	Date of factory recertification (R).
	Latex free.
	Disposable. Single patient use only.
	Tear here to open.
	Do not recharge battery.
	Position of pads on the chest of patient.
	For use by or on the order of a Physician, or persons licensed by state law.
	Dispose of properly in accordance with all state, province, and country regulations.

Symbol	Description
	Do not incinerate or expose to open flame.
	Explosion hazard: Do not use in the presence of a flammable gas, including concentrated oxygen.
	Upper and lower temperature limits.
	Serial Number.
	Device model number, battery model number.
	Lot number
	Option number
	Lithium sulfur dioxide

Symbol	Description
	Serial communication port
	Additional information is provided in the AED Operation and Service Manual.
	Manufacturer
	Authorized representative in the European Community
	Waste Electronic Electrical Equipment (WEEE). Separate collection for waste electrical and electronic equipment.

Electromagnetic Emissions Standards Compliance

Guidance and manufacturer's declaration—electromagnetic emissions

The AED is intended for use in the electromagnetic environment specified below. The customer or the user of the AED should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment—guidance
RF emissions CISPR 11	Group 1	The AED uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The AED is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration—electromagnetic immunity

The AED is intended for use in the electromagnetic environment specified below. The customer or the user of the AED should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	Not applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec.	Not applicable	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	80 A/m	Power frequency magnetic fields should be at levels no higher than those characteristic of a typical location in typical heavy industrial and power plants and the control rooms of H.V. sub-stations.

Note: UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration—electromagnetic immunity

The AED is intended for use in the electromagnetic environment specified below. The customer or the user of the AED should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the AED, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance
Conducted RF	3 Vrms	Not Applicable	
IEC 61000-4-6	150 kHz to 80 MHz outside ISM bands[a]		
	10 Vrms 150 kHz to 80 MHz in ISM bands[a]	Not Applicable	

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Radiated RF	10 V/m	10 V/m	d = 1.2 $\sqrt{P}$ 80 MHz to 800 MHz
IEC 61000-4-3	80 MHz to 2.5 GHz		d = 2.3 $\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m)[b]. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
a	The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 to 40.70 MHz.		
b	The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.		
c	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the AED is used exceeds the applicable RF compliance level above, the AED should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the AED.		
d	Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 1 V/m.		

Recommended separation distances between portable and mobile RF communications equipment and the AED

The AED is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the AED can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the AED as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter m			
W	150 kHz to 80 MHz outside ISM bands	150 kHz to 80 MHz in ISM bands	80 MHz to 800 MHz	800 MHz to 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.38	0.38	0.38	0.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 to 40.70 MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

2 Introduction

What's in this chapter

- AED Description
- Indications for use
- RHYTHMx AED ECG Analysis Algorithm
- Rescue Protocol
- STAR Biphasic Waveform
- STAR Biphasic Energy Protocols for Powerheart G3 AEDs
- Operator Training Requirements

This section presents information about the AED, its use, and the training requirements for operation.

AED Description

The AED is a self-testing, battery-operated automated external defibrillator (AED). After applying the AED's electrodes (pads) to the patient's bare chest, the AED automatically analyzes the patient's electrocardiogram (ECG) and advises the operator to press the button and deliver a shock if needed. The AED uses one button and guides the operator through the rescue using a combination of voice prompts, audible alerts, and visible indicators. For the Powerheart AED G3 Automatic, the AED automatically delivers a shock if needed.

Indications for use

The Powerheart AED G3 and the Powerheart AED G3 Automatic devices are intended to be used by personnel who have been trained in its operation. The user should be qualified by training in basic life support or other physician-authorized emergency medical response.

The device is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing.

Post-resuscitation, if the victim is breathing, the AED should be left attached to allow for acquisition and detection of the ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will charge automatically and advise the operator to deliver therapy (G3) or automatically deliver the shock (G3 Automatic).

When a patient is a child or infant up to 8 years of age, or up to 55 lbs (25kg), the device should be used with the Model 9730 Pediatric Attenuated Defibrillation Electrodes. The therapy should not be delayed to determine the patient's exact age or weight.

RHYTHMx AED ECG Analysis Algorithm

The RHYTHMx™ AED ECG analysis algorithm provides ECG detection capabilities. The features available with the AED include the following:

- Detection Rate
- Asystole Threshold
- Noise Detection
- Non-Committed Shock
- Synchronized Shock
- Pacemaker Pulse Rejection
- SVT Discriminators
- Supraventricular Tachycardia (SVT) Rate

Detection Rate

All ventricular fibrillation (VF) and ventricular tachycardia (VT) rhythms at or above this rate will be classified as shockable. All rhythms below this rate will be classified as non-shockable. This rate is programmable between 120 bpm (beats per minute) and 240 bpm via MDLink Software by the Medical Director. The default Detection Rate is 160 bpm.

Asystole Threshold

The asystole baseline-to-peak threshold is set at 0.08 mV. ECG rhythms at or below 0.08 mV will be classified as asystole and will not be shockable.

Noise Detection

The AED will detect noise artifacts in the ECG. Noise could be introduced by excessive moving of the patient or electronic noise from external sources like cellular and radiotelephones. When noise is detected, the AED will issue the prompt “ANALYSIS INTERRUPTED. STOP PATIENT MOTION” to warn the operator. The AED will then proceed to reanalyze the rhythm and continue with the rescue.

Non-Committed Shock

After the AED advises a shock, it continues to monitor the patient ECG rhythm. If the patient’s rhythm changes to a non-shockable rhythm before the actual shock is delivered, the AED will advise that the rhythm has changed and issue the prompt “RHYTHM CHANGED. SHOCK CANCELLED.” The AED will override the charge and continue ECG analysis.

Synchronized Shock

The AED is designed to automatically attempt to synchronize shock delivery on the R-wave if one is present. If delivery cannot be synchronized within one second, a non-synchronized shock will be delivered.

Pacemaker Pulse Detection

The AED contains pacemaker pulse detection circuitry to detect pulses from an implanted pacemaker.

SVT Discriminators

The AED is supplied with the SVT Discriminator enabled and with the default setting “NO THERAPY FOR SVT”. With the factory default setting of “NO THERAPY FOR SVT”, the AED will not shock an SVT rhythm.

SVT Discriminators are sophisticated filters that analyze the morphology of the ECG waveforms and distinguish VF/VT from SVT and Normal Sinus Rhythms (NSR). The SVT Discriminator will only be applied to rhythms that fall between the Detection Rate and the SVT Rate. The factory default setting for this feature is “NO THERAPY FOR SVT”, however the Medical Director can enable this feature using MDLink on the Powerheart AED.

SVT Rate

All rhythms with rates between the Detection Rate and SVT Rate will be screened through a number of SVT Discriminators to classify them into VF/VT or SVT. Rhythms classified as SVT between the two set rates are not shockable. All SVT rhythms above the rates will be classified as shockable. The SVT Rate must be greater than the Detection Rate and is selectable between 160 and 300 bpm or, "NO THERAPY FOR SVT" can be selected via MDLink Software by the Medical Director.

Rescue Protocol

The AED rescue protocol is consistent with the guidelines recommended by the American Heart Association (*Guidelines 2005 for Cardiopulmonary Resuscitation and Emergency Cardiac Care* American Heart Association; Circulation vol 112, Issue 24 Suppl. Dec. 13, 2005) and the International Liaison Committee on Resuscitation (ILCOR)).

Upon detecting a shockable cardiac rhythm, the AED advises the operator to press the SHOCK button (9390E only) to deliver a defibrillation shock followed by performing 2 minutes of CPR.

For the Powerheart AED G3 Automatic, upon detecting a shockable rhythm, the AED will automatically deliver a defibrillation shock followed by performing 2 minutes of CPR.

Note: In alignment with the 2005 Guidelines, the default setting for the CPR time has been set to allow for 5 cycles of 30 compressions and 2 breaths. Increasing or decreasing the CPR time setting may increase or decrease the number of actual cycles allowed during the CPR time period.

STAR Biphasic Waveform

The STAR® Biphasic Waveform is designed to measure the patient's impedance and deliver a customized shock. This allows the delivery of an optimized energy level to each patient. The energy levels for the Powerheart G3 AED are available in three different defibrillation shock levels.

The ultra-low current, low current, and high current shocks are variable energy. The actual energy is determined by the patient's impedance. See Table 1 on page 2-5, Table 13 on page 7-9, Table 14 on page 7-9, and Table 15 on page 7-10 for additional information.

STAR Biphasic Energy Protocols for Powerheart G3 AEDs

The STAR Biphasic defibrillation waveform will deliver variable escalating energy that is customized to each patient's needs based upon a patient's thoracic impedance. This customization adjusts for the unique physical differences between patients. The range of impedance over which the device will deliver a shock is 25-180 Ohms. The Powerheart G3 AED comes equipped with five different FDA cleared biphasic energy protocols.

The operator, with guidance, direction, and implementation from the designated AED program Medical Director, may select from one of these five protocols when placing the Powerheart G3 AED into service. The Powerheart G3 AED's factory default energy protocol is 200-300-300 Joule (J) escalating Variable Energy (VE). The first shock is delivered within the range of 140J-250J (200J nominal). Subsequent shocks are delivered within a range of 190J-360J (300J nominal).

These protocols are selected by using the MDLink software program. The five biphasic energy protocols available are as follows:

Table 1: Biphasic Energy Protocols

Energy Protocols	Shock Sequence[1]	Energy Level (VE)	Energy Range (J)
Factory Default	1	200	140-250
	2	300	190-360
	3	300	190-360
Protocol #2	1	200	140-250
	2	200	140-250
	3	300	190-360
Protocol #3	1	150	105-195
	2	200	140-250
	3	200	140-250
Protocol #4	1	150	105-195
	2	150	105-195

Table 1: Biphasic Energy Protocols

Energy Protocols	Shock Sequence[1]	Energy Level (VE)	Energy Range (J)
	3	200	140-250
Protocol #5	1	200	140-250
	2	200	140-250
	3	200	140-250

[1]The ultra-low energy, low energy, and high energy shocks are variable energy. The actual energy is determined by the patient's impedance.

Operator Training Requirements

Persons authorized to operate the AED must have all of the following minimum training.

- Defibrillation training and other training as required by state, province, or country regulations
- Training on operation and use of the AED
- Additional training as required by the physician or Medical Director
- A thorough understanding of the procedures in this manual

Note: Keep valid certificates of training and certification as required by state, province, or country regulations.

3 Getting Started

What's in this chapter

- Unpacking and Inspecting
- AED Parts
- AED Modes
- IntelliSense Battery
- Pads
- AED Indicators
- Setting the AED Internal Clock
- Voice Prompts and Text Display

This section presents information on unpacking and setting up the AED.

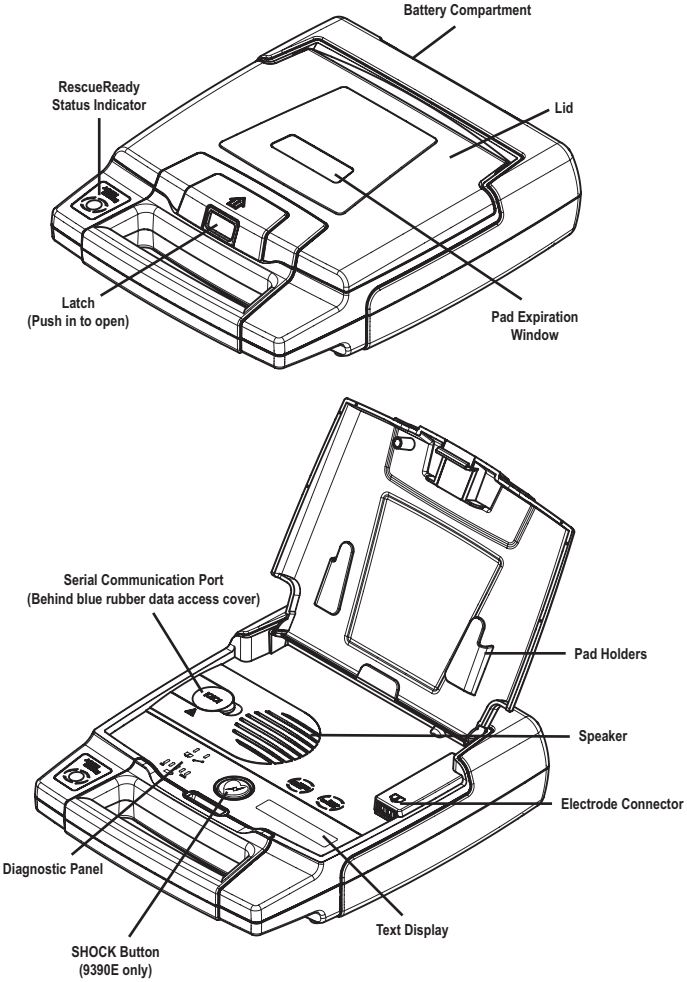
Unpacking and Inspecting

Every attempt is made to ensure your order is accurate and complete. However, to be sure that your order is correct, verify the contents of the box against your packing slip.

If you have any questions about your order, contact Customer Service (see *Contact Information* on page 1-1).

AED Parts

The following drawings show the AED parts and their locations.



AED Modes

Operating Mode: Defined as having the battery installed and the lid open. This is the mode the AED would be in during an actual rescue situation.

Standby Mode: When the battery is installed, but the lid is closed. In this mode the AED is not being used in a rescue. The device will conduct its routine self-tests to ensure proper operation.

Storage Mode: When the battery is removed, such as during shipping or transport. With the battery removed, the AED is unable to perform self-tests or rescues.

Environmental Operating and Standby Conditions

See Chapter 7, *Technical Data*.

Caution. Temperature Extremes.

Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The RescueReady® daily self-test verifies the impact of extreme environmental conditions on the AED. If the daily self-test determines environmental conditions outside of the AED's operating parameters, a "Service Required" alert will be issued to prompt the user to move the AED to environmental conditions within the acceptable operating parameters at once.

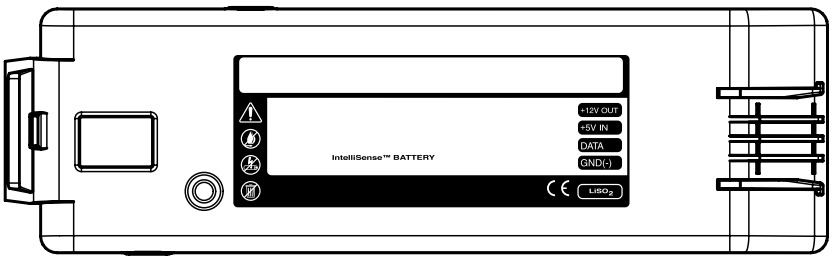
Shipping and Transport Conditions

(For up to 1 week)

See Chapter 7, *Technical Data*.

IntelliSense Battery

IntelliSense batteries contain an integrated memory chip that automatically stores important usage information, enabling the battery to maintain a complete history of its operating life. The actual battery history can be reviewed using the RescueLink software.



This history includes:

- Battery Identification
- Battery Type
- Original Date of Installation in an AED
- Number of Charges completed
- Time in Operation (hours:minutes)
- Days of Standby Operation
- Battery Capacity Remaining

Warning. Battery is Not Rechargeable.

Do not attempt to recharge the battery. Any attempt to recharge the battery may result in an explosion or fire hazard.

Caution. Lithium Sulfur Dioxide Battery.

Pressurized contents: never recharge, short circuit, puncture, deform, or expose to temperatures above 65°C (149°F). Remove the battery when discharged.

Caution. Battery Disposal.

Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

Caution. Use only Cardiac Science Approved Equipment.

Using batteries, pads, cables, or optional equipment other than those approved by Cardiac Science may cause the AED to function improperly during a rescue.

Caution. Possible Improper AED Performance.
Using pads that are damaged or expired may result in improper AED performance.

Note: Battery part number 9146 is only for use with the Powerheart AED G3 and Powerheart AED G3 Automatic.

Battery Operating Life

The battery operating life depends on the type of battery, actual usage and environmental factors.

The following table represents the expected life of the Powerheart G3 AED when used in Standby Mode.

Table 2: Normal Battery Operating Life

Model	Estimated Shelf Life (from date of manufacture)	Full Operational Replacement Guarantee (from date of installation)	Typical Shocks
9146 Lithium (p/n: 9146-001)	5 Years	4 Years	up to 290

Battery Shelf Life

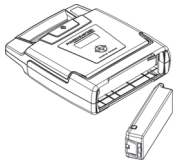
The batteries have a shelf life of five years. Shelf life is defined as the length of time a battery can be stored, prior to installation into AED, without degrading its performance.

Note: Storing the battery outside its specific range (0-50°C) will decrease battery life.

Battery Installation

To install the battery:

1 With the label on the battery facing the AED battery compartment, insert the battery as shown in the drawing.



2 Push the latched end of the battery firmly into the AED, as shown in the drawing, until the battery snaps into place. The exposed side of the battery should be flush with the outside of the AED case.

3 For the Powerheart AED, open the lid for 5 seconds to initiate self-test. If the battery is installed properly, the STATUS INDICATOR will turn GREEN. Close the lid.

OR

Open the lid for 5 seconds to initiate a self-test. If the battery is installed properly, the SMARTGAUGE battery indicator LEDs will illuminate; additionally, the STATUS INDICATOR will turn GREEN. If service is required, then the SERVICE indicator will illuminate.

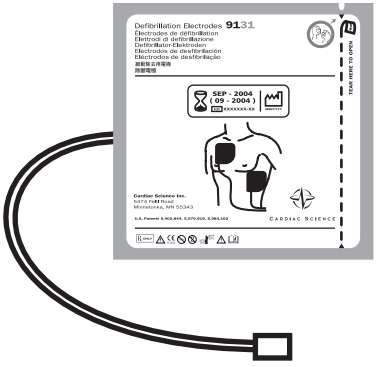
RESCUE READY®

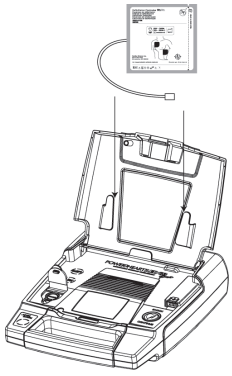
Pads

The defibrillation pads come in a ready-to-use, sealed package containing one pair of self-adhesive pads with an attached cable and connector. The pads are disposable and should be discarded after each rescue.

The pads have a limited shelf life and should not be used beyond the expiration date. Keep a fresh, unopened pair of pads plugged into the AED at all times. Refer to the pad package label for operation temperatures.

An audible and visual alert will indicate after the self-test if the pads are missing, unplugged, or damaged.





Pad Installation

To install the pads:

1. Open the lid of the AED.
2. Place the pad package into the lid so that the expiration label is visible through the clear window on the lid. The expiration date of the pads will then be readable without opening the lid of the AED.
3. Match the color of the connectors (red to red), then plug the pad connector into the AED case as shown in the drawing. Once the pad connector is plugged into AED, the PAD indicator should extinguish.
4. Tuck the excess cable length in the bottom holder as shown in the drawing. With the pad package completely secured to the AED lid, close the lid.
5. Make sure the expiration date is visible through the clear window of the lid and check to make sure that the STATUS INDICATOR is GREEN. If the pads are not installed properly, the STATUS INDICATOR will be RED. Call Customer Service for assistance.

Caution. Use only Cardiac Science Approved Equipment.

Using batteries, pads, cables, or optional equipment other than those approved by Cardiac Science may cause the AED to function improperly during a rescue.

Caution. Possible Improper AED Performance.
Using pads that are damaged or expired may result in improper AED performance.

Directions for Use

Pads are for short term use only. Do not open until ready to use.

Caution. Equipment Damage.
Do not pull on the lead wire to separate the pads from the blue liner. Follow directions on the pad packaging:

1. Ensure the skin site is clean and dry.
2. Separate one pad from blue liner.
3. Place one pad on bare skin in either location.
4. Peel and place remaining pad in opposite location.

AED Indicators

The following indicators are located on the AED.

RescueReady Status Indicator

The STATUS INDICATOR is located on the Powerheart G3 AED handle.

When this indicator is GREEN, the AED is RescueReady. This means the AED self-tests have verified the following:

- Battery has an adequate charge
- Pads are properly connected to the AED and functioning
- Integrity of the internal circuitry is good

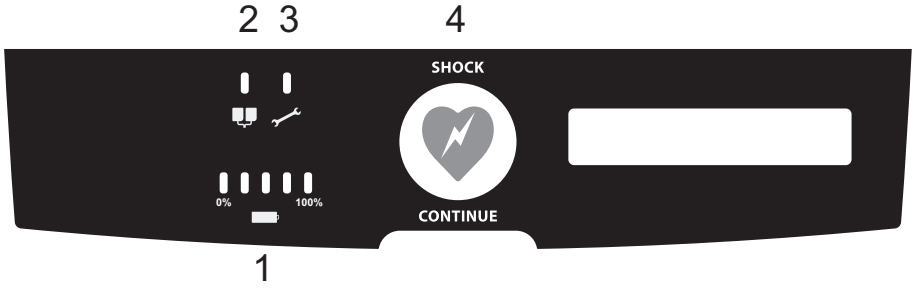
When the STATUS INDICATOR is RED, maintenance is required.

Audible Maintenance Indicator

When the daily, weekly, or monthly self-test determines service is required, an audible beep is sounded every 30 seconds until the lid is opened or the battery power is depleted. Opening and closing the lid may deactivate the beep. If the error is not corrected by the next automatic self-test, the beep will be reactivated.

Diagnostic Panel

The diagnostic panel has the following indicators:



1 SmartGauge Battery Indicator

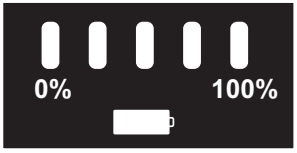
2 Pads Indicator

3 Service Indicator

4 Shock Button (Powerheart G3 model 9390E only)

SmartGauge Battery Status Indicator

The SmartGauge Battery Status Indicator has five LEDs, four green and one red. The right four green LEDs display the remaining capacity of the battery much like a fuel gauge. With use, the green LEDs gradually go out, from right to left, as battery capacity decreases. When the green LEDs go out and the red LED lights up, replace the battery.

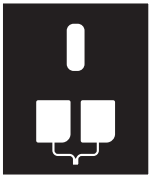


Note: When the red LED initially lights up–upon lid opening or at any time during a rescue–a "BATTERY LOW" prompt will be issued at once. However, the AED is capable of delivering at least 9 more defibrillation shocks after the first "Battery Low" prompt is issued.

When the AED battery cannot deliver any more shocks, the AED shows "BATTERY LOW" on the text display, and the red battery LED illuminates. To continue the rescue, leave the lid open, remove the battery, and replace with a fresh battery. If battery replacement takes longer than 60 seconds, the first rescue will be terminated and a second rescue will begin upon insertion of battery.

Pads Indicator

The Pads LED lights up when the pads are:



- Not properly connected to the AED
- Not within operational specifications (cold, dried, damaged)
- Disconnected from the patient during a rescue

Service Indicator

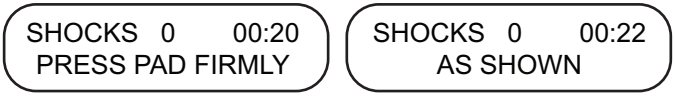
The Service LED lights up when the AED requires maintenance that can only be performed by qualified service personnel.

Shock Indicator

For the Powerheart G3 model 9390E only: The AED has one button called the Shock/Continue button. The word Shock and the shock button indicator LED will illuminate red when the AED is ready to deliver a defibrillation shock to the patient.

Text Display

The text display has 2 lines of text. The text display provides the operator with information regarding system initialization, text prompts and data during a rescue, and diagnostics.



System initialization occurs when the lid is first opened. The text display shows the operator the identifiers for the internal code, voice prompts and text prompts versions. The text display also shows the current date and time.

During a rescue, the text display shows the number of shocks delivered and the elapsed time from the beginning of the rescue (when the lid was first opened). During CPR, a countdown timer will be displayed. The text version of the voice prompts will also be displayed.

Note: There is a 3 second delay between the time the AED lid is opened and the start of the rescue. This 3 second delay is not included in the elapsed rescue time.

Setting the AED Internal Clock

The internal clock is preset at Central Standard Time and should be reset to the correct date and local time. If applicable, the AED will automatically adjust itself for Daylight Savings Time. This feature can be turned off using the MDLink software. To set the clock, you will need a Windows 98 or newer PC, RescueLink software installed, and the AED serial cable connected to the PC.

To set the clock settings:

1. Ensure that the PC is set at the correct local time and date.
2. Open the lid of the AED and run the RescueLink software on the PC.
3. Connect the cable to the serial port on the AED.
4. Verify that the voice prompt states “Communications Mode”.
5. Click Communications on the main menu. Select AED Date and Time.
6. Click on the Get button to review the current time in the AED.
7. If the time and date is incorrect, click Set to set new time and date. The AED date and time will automatically be updated to the PC’s time and date.

Voice Prompts and Text Display

The voice prompts activate when the AED lid is opened and help guide the operator through the rescue. The AED text display provides a visual display of most of the audible voice prompts.

The following table lists the voice and text prompts and a description of when the prompts are issued.

Table 3: Initial Instructions

Voice Prompt	Text Display	Situation
"Stay Calm. Follow These Voice Instructions. Make Sure 911 is Called Now!"	CALL 911!	Plays after lid opening self test, default ON.
"Stay Calm. Follow These Voice Instructions. Make Sure Emergency Services are Called Now!"	CALL EMERGENCY SERVICES NOW!	Medical Director may use MDLink to select this prompt instead of "CALL 911!". MDLink also allows the emergency services and 911prompt to be disabled.

Table 4: Preparation

Voice Prompt	Text Display	Situation
"Begin by Exposing Patient's Bare Chest and Torso. Remove or Cut Clothing if Needed."	BARE PATIENT'S TORSO REMOVE CLOTHING	Prompts the rescuer to remove patient clothing.
"When Patient's Chest and Torso are Exposed, Remove Square Foil Package from Lid of AED."	WHEN CHEST IS BARE REMOVE FOIL PACKAGE	Prompts the rescuer to remove the pads from AED lid.
"Tear Open Foil Package Across Dotted Line and Remove Pads."	TEAR OPEN PACKAGE REMOVE PADS	Prompts the rescuer to open the pad package and remove pads.
"Next, Separate One of the White Pads Completely from Blue Plastic Liner. Begin Peeling from the Tabbed Corner."	PEEL ONE PAD FROM BLUE PLASTIC LINER	Repeats every 3 seconds until the pads are separated. If a pad has been peeled before the prompt starts, this prompt will be skipped. This prompt will be interrupted when pad is peeled.

Table 4: Preparation (continued)

Voice Prompt	Text Display	Situation
"Firmly Place the Pad Without the Liner on the Patient, Exactly as Illustrated. This Pad Can be Placed on Either of the Two Locations Shown."	PRESS PAD FIRMLY TO CHEST AS SHOWN	Prompts the rescuer to place one pad on the patient.
"Next, Peel the Blue Plastic Liner Off of the Second White Pad."	PEEL SECOND PAD OFF BLUE PLASTIC LINER	Prompts the rescuer to remove the liner from the second pad.
"Firmly Place the Second Pad on the Opposite Location, Exactly as Illustrated."	PRESS PAD FIRMLY AS SHOWN	Repeats until second pad placement is sensed. If the pad is placed before prompt starts then this prompt will be skipped. This prompt will be interrupted when second pad is placed.

Table 5: Analysis

Voice Prompt	Text Display	Situation
"Do Not Touch Patient! Analyzing Heart Rhythm. Please Wait."	DO NOT TOUCH PATIENT ANALYZING RHYTHM	Repeats until analysis of the patient's cardiac rhythm is completed. This prompt will be interrupted when ready to shock.
"Preparing Shock. Move Away from the Patient!"	NO CONTACT WITH THE PATIENT	Repeats while the AED is preparing to deliver a defibrillation shock (charging).

Table 6: Delivering Shock - Semi-Automatic

Voice Prompt	Text Display	Situation
"Press Red Flashing Button to Deliver Shock."	PRESS BUTTON TO DELIVER SHOCK	Prompts after the AED is fully charged and ready to deliver the defibrillation shock. The RED SHOCK indicator flashes and the phrase repeats for 30 seconds or until the SHOCK button is pushed.
"Shock Delivered"	SHOCK DELIVERED	Prompts when the shock is delivered.

Table 7: Delivering Shock - Fully Automatic

Voice Prompt	Text Display	Situation
"Shock Will be Delivered in"	SHOCK IN:	After the AED is fully charged and ready to deliver the defibrillation shock. The SHOCK will automatically be administered approximately three seconds after the end of the voice prompt.
"Three"	THREE	Prompts approximately three seconds prior to delivering shock.
"Two"	TWO	Prompts approximately two seconds prior to delivering shock.
"One"	ONE	Prompts approximately one second prior to delivering shock.
"Shock Delivered"	SHOCK DELIVERED	Prompts when the shock is delivered.

Table 8: CPR Prompts

Voice Prompt	Text Display	Situation
Note: The AED is shipped from the factory with ENHANCED MODE defaulted ON. The Medical Directory may modify the CPR options in MDLink. ENHANCED CPR prompts are listed below.		
"It is Now Safe to Touch the Patient."	NOW SAFE TO TOUCH THE PATIENT	Advises the rescuer that it is safe to touch the patient: • After the AED delivers a shock • After the AED detects a non-shockable cardiac rhythm
"When instructed, give 30 Rapid Compressions then give 2 Breaths"	30 COMPRESSIONS 2 BREATHS	Prompts rescuer to correctly give compressions and breaths.
"Place Heel of One Hand on Center of Chest Between Nipples."	PLACE ONE HAND ON CENTER OF CHEST	Prompts rescuer to correctly place one hand for giving compressions.
"Place Heel of Other Hand Directly on Top of First Hand. Lean Over Patient with Elbows Straight."	PLACE OTHER HAND ON TOP OF FIRST HAND	Prompts rescuer to correctly place other hand and body for giving compressions.

Table 8: CPR Prompts (continued)

Voice Prompt	Text Display	Situation
"Press the Patient's chest down rapidly one third depth of chest, then release"	PRESS CHEST DOWN FIRMLY	Prompts the rescuer to press down one third depth of patient's chest.
"Start CPR"	START CPR	Prompts to start CPR.
"Press" (30 times at 100/ minute) (or) Metronome (30 times at 100/minute) (or) No Prompt (silence) **Note:** Option is selected in MDLink software.	{CPR COUNTER}	CPR counter shows the amount of time remaining for the CPR session.
"Stop Compressions"	STOP COMPRESSIONS	Prompts at the end of each CPR round.
"Give Breath, Give Breath"	GIVE BREATH	Prompts to give two breaths to patient.
"Continue with Compressions."	CONTINUE WITH COMPRESSIONS	Prompts in subsequent rounds of the same CPR session. **Note:** This prompt is available only in Enhanced Mode.
"Stop CPR"	STOP CPR	Prompts to stop CPR.
"Continue CPR"	CONTINUE CPR	Prompts when Enhanced Mode is not selected in MDLink. Prompts when lid is reopened during CPR cycle.

Table 9: Pad Issues

Voice Prompt	Text Display	Situation
"Make Sure Pad Connector is Plugged into AED."	CHECK CONNECTOR IS PLUGGED INTO AED	Prompts when defibrillation pads connector is not correctly inserted into pad socket.

Table 9: Pad Issues

Voice Prompt	Text Display	Situation
"Press Pads Firmly to Patient's Bare Skin."	PRESS PADS FIRMLY TO BARE SKIN	Prompts when better pad connectivity to the patient's skin is required because impedance is too high.

Table 10: Other Prompts

Voice Prompt	Text Display	Situation
"Battery Low"	BATTERY LOW	Occurs once when the battery voltage becomes low, although a rescue can continue for approximately 9 more shocks. When the battery is too low to do a rescue, the following will occur: **1** "BATTERY LOW" will show on the LCD **2** STATUS INDICATOR will turn RED **3** AED will BEEP once every 30 seconds You must replace the battery before continuing with the rescue. If completely depleted, all AED activity will terminate.
"Analysis Interrupted. Stop Patient Motion."	ANALYSIS INTERRUPTED STOP PATIENT MOTION	When the AED detects ECG noise artifact, stop moving or touching the patient. Remove other electronic devices within a 5 meter radius.
"Open Lid to Continue Rescue."	OPEN LID TO CONTINUE RESCUE	When the lid is inadvertently closed during a rescue, this prompt will repeat for 15 seconds.
"Rhythm Changed. Shock Cancelled."	RHYTHM CHANGED SHOCK CANCELLED	When the device is prepared to shock then detects a change in rhythm and therefore cancels the shock.
"Remove Cable to Continue Rescue."	REMOVE CABLE TO CONTINUE RESCUE	When a serial communication cable is connected to the AED during a rescue, the phrase repeats until the cable is disconnected.

Table 10: Other Prompts (continued)

Voice Prompt	Text Display	Situation
"Communications Mode"	COMMUNICATIONS MODE	When the lid is open and the serial communication cable is plugged into the AED.
"Service Required"	SERVICE REQUIRED	Occurs after the self-tests determine that the AED is not functioning properly. The prompt "SERVICE REQUIRED" will be heard when the lid is opened. The red SERVICE indicator will illuminate and "SERVICE REQUIRED" will repeat until you close the lid. After closing the lid, an alarm beep will be heard until the battery is removed or becomes completely depleted.

4 Instructions For Use

What's in this chapter

- Warnings and Cautions
- Step 1: Patient Preparation
- Step 2: Place Pads
- Step 3: ECG Analysis
- Step 4: Shock Delivery
- Step 5: CPR Mode
- Step 6: Post Rescue

This section presents information about how to use the AED to perform a rescue.

Warnings and Cautions

The following cautions must be observed to prevent problems during the rescue.

DANGER: Fire and Explosion Hazard

Do not use in the presence of flammable gasses (including concentrated oxygen) to avoid possible explosion or fire hazard.

WARNING: Shock Hazard

Defibrillation shock current flowing through unwanted pathways is potentially a serious electrical shock hazard. To avoid this hazard during defibrillation abide by all of the following:

- Do not touch the patient, unless performance of CPR is indicated
- Do not touch metal objects in contact with the patient
- Keep defibrillation pads clear of other pads or metal parts in contact with patient
- Disconnect all non-defibrillator proof equipment from the patient before defibrillation

WARNING: Shock and Possible Equipment Damage

Disconnect all non-defibrillator proof equipment from the patient before defibrillation to prevent electrical shock and potential damage to the equipment.

WARNING: Electric Shock and Fire Hazard

Do not connect any telephones or unauthorized connectors to the socket on this equipment.

CAUTION: Use only Cardiac Science Approved Equipment

Using batteries, pads, cables, or optional equipment other than those approved by Cardiac Science may cause the AED to function improperly during a rescue.

CAUTION: Possible Improper AED Performance

Using pads that are damaged or expired may result in improper AED performance.

CAUTION: Serial Communication Cable

The AED will not function during a rescue when the serial communication cable is connected to its serial port. When the serial communication cable is connected to the AED during a rescue, the prompt "Remove cable to continue rescue" will be heard until you remove the serial communication cable from the AED.

CAUTION: Possible Radio Frequency (RF) Susceptibility

RF susceptibility from cellular phones, CB radios, and FM 2-way radio may cause incorrect rhythm recognition and subsequent shock advisory. When attempting a rescue using the AED, do not operate wireless radiotelephones within 1 meter of the AED – turn power OFF to the radiotelephone and other like equipment near the incident.

CAUTION: Possible Interference with Implanted Pacemaker

Therapy should not be delayed for patients with implanted pacemakers and a defibrillation attempt should be made if the patient is unconscious and not breathing. The AED has pacemaker detection and rejection, however with some pacemakers the AED may not advise a defibrillation shock.

When placing pads:

- Do not place the pads directly over an implanted device.
- Place the pad at least an inch from any implanted device.

CAUTION: Moving the Patient During a Rescue

During a rescue attempt, excessive jostling or moving of the patient may cause AEDs to improperly analyze the patient's cardiac rhythm. Stop all motion or vibration before attempting a rescue.

Step 1: Patient Preparation

Determine that the patient is over 8 years of age or weighs more than 55 pounds (25 kg) and is both:

- Unresponsive
- Not breathing

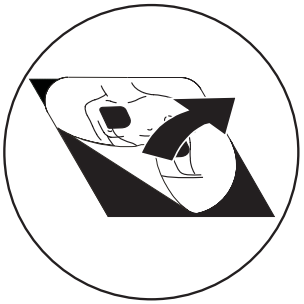
Open the AED lid and wait until the LEDs are lit. The AED will prompt "Stay Calm. Follow these voice instructions. Make sure 911 is called now."

The AED will prompt "Begin by Exposing the Patient's Bare Chest and Torso. Remove or Cut Clothing if Needed." Remove clothing from the patient's chest. Ensure the skin site is clean and dry. Dry the patient's chest and shave excessive hair if necessary.

Note: When the patient is a child under 8 years of age or weighs less than 55 lbs (25kg), the AED should be used with the Model 9730 Pediatric Attenuated Defibrillation Pads. Therapy should not be delayed to determine the patient's exact age or weight. See the directions for use accompanying pediatric pads for procedure on changing adult pads to pediatric.

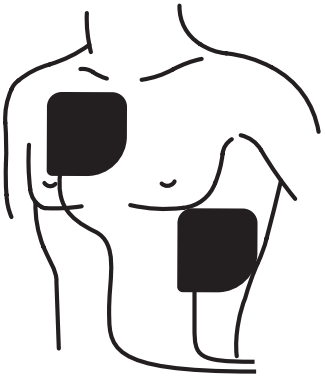
Step 2: Place Pads

The AED will prompt "When Patient's Chest and Torso are Exposed, Remove Square Foil Package from Lid of AED. Tear Open Foil Package Across Dotted Line and Remove Pads." Keep the pads connected to the AED, tear the package along the dotted line and remove the pads from the package. Leave the package attached to the pad wires.



After the prompt, “Next, Separate One of the White Pads Completely from Blue Plastic Liner. Begin Peeling from the Tabbed Corner,” with a firm, steady pull, carefully peel one pad away from the blue release liner.

Then, “Firmly Place the Pad Without the Liner on the Patient, Exactly as Illustrated. This Pad Can be Placed on Either of the Two Locations Shown.”



After the prompt “Next, Peel the Blue Plastic Liner Off of the Second White Pad. Firmly Place the Second Pad on the Opposite Location, Exactly as Illustrated,” pull the blue liner from the second pad and place in the opposite position indicated.

Note: Cardiac Science’s standard defibrillation pads are non-polarized and can be placed in either position as shown on the pad package.

Step 3: ECG Analysis

When the pads are placed, the AED will prompt “Do Not Touch Patient. Analyzing Heart Rhythm. Please Wait.” The AED will begin to analyze the cardiac rhythm of the patient.

If the pads become disconnected from the AED, the prompt “Make sure pad connector is plugged into AED” will be heard. If this occurs, check to be sure the connector is properly plugged into the AED. If the pads are not properly placed or become loose during the rescue, the voice prompt “Press pads firmly to patient’s bare skin” will be heard. When this occurs, ensure that pads are firmly placed on clean, dry skin.

If noise is detected during analysis, the AED will warn you with the prompt “Analysis Interrupted. Stop Patient Motion” and restart the analysis. This usually occurs if the patient is excessively jostled or there is a strong electromagnetic emitting electronic device nearby (within 5 meters). Remove the electronic device or stop the excessive motion if you hear this prompt.

Step 4: Shock Delivery

If a shock is advised, the voice prompt will say, “Preparing Shock. Move away from the patient.”

You should ensure that you and any bystanders are not touching the patient.

For the Powerheart AED G3: When the AED is ready to deliver a defibrillation shock, the Shock button will flash and the prompt “Press Red Flashing Button to Deliver Shock” will be heard. Make sure no one is touching the patient and press the Shock button to deliver a defibrillation shock. If you do not press the Shock button within 30 seconds of hearing the prompt, the AED will disarm and prompt you to start CPR.

For the Powerheart AED G3 Automatic: When the AED is ready to deliver a shock, the voice prompt, “Shock Will be Delivered in Three, Two, One” then deliver a shock. Make sure no one is touching the patient.

Both models: After the AED delivers the defibrillation shock, the voice prompt will say “Shock Delivered,” and prompt you to start CPR.

When the AED is charged, it continues to analyze the patient's heart rhythm. If the rhythm changes and a shock is no longer needed, the AED will issue

the prompt “Rhythm Changed. Shock Cancelled,” and prompt you to start CPR.

Note: During a rescue, the text screen displays voice prompts, elapsed time of rescue and number of shocks delivered.

Step 5: CPR Mode

The voice prompt will say, “It is now safe to touch the patient.”

The AED will then continue on with instructions for delivery of chest compressions, beginning with, “Place heel of one hand on center of chest between nipples. Place heel of other hand directly on top of first hand. Lean over patient with elbows straight. Press the patient’s chest down rapidly one-third depth of chest, then release.”

If this is not the first delivery of CPR, then the AED will prompt, “When instructed give 30 rapid compressions. Then give two breaths. Start CPR.”

At the end of the compressions, the phrase “Stop compressions” will play.

The AED will then continue with the prompt, repeating “Give Breath” twice. Following this, the phrase “Continue with compressions.”

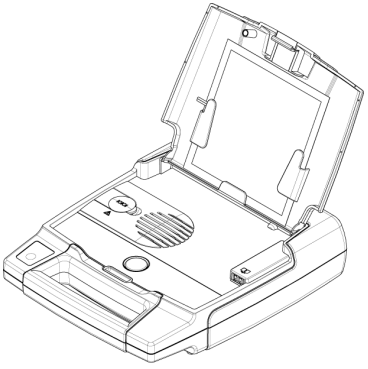
This cycle will continue until the CPR time expires. At the end of CPR, the phrase “Stop CPR” will be played. The AED will return to the ECG Analysis Mode (see *Step 3: ECG Analysis* on page 4-5).

If the patient is conscious and breathing normally, leave the pads on the patient's chest connected to the AED. Make the patient as comfortable as possible and wait for Advanced Life Support (ALS) personnel to arrive.

Continue to follow the voice prompts until the ALS personnel arrive, or proceed as recommended by the Medical Director.

Step 6: Post Rescue

After transferring the patient to ALS personnel, prepare the AED for the next rescue:



1. Retrieve the rescue data stored in the internal memory of the AED by using RescueLink software installed on a PC (see detailed procedure in the Data Management section).
2. Connect a new pair of pads to the AED.
3. Close the lid.
4. Verify that the Status Indicator on the handle is green.

5 Data Management

What's in this chapter

- Recording Rescue Data
- Reviewing Rescue Data

The AED is designed for ease of data management and review. The data stored in internal memory can be displayed on the PC screen using the RescueLink software.

Recording Rescue Data

The AED can store up to 60 minutes of ECG monitoring time in the AED's internal memory. Multiple rescues can be stored in the internal memory, allowing the rescuer to administer additional rescues without downloading the data to a PC. Should the internal memory become full, the AED will purge rescues as needed, beginning with the oldest rescue.

When downloading data, RescueLink will enable the user to select which rescue to download. See the RescueLink application HELP files for more information.

Reviewing Rescue Data

To retrieve data from internal memory:

1. Open the AED lid.
2. Connect the serial cable to the PC and to the AED's serial port under the blue rubber data access cover. The voice prompt will say "Communications Mode."
3. Run the RescueLink software program.
4. Select Communications, Get Rescue Data.
5. Select Internal Memory of AED then select OK.
6. Select a rescue by clicking on the date and press OK.

WARNING: Electric Shock and Fire Hazard.

Do not connect any telephones or unauthorized connectors to the socket on this equipment.

CAUTION: Serial Communication Cable.

The serial communication cable is only for use with the AED; it is not to be used with a telephone.

6 Maintenance and Troubleshooting

What's in this chapter

- Self-Tests
- Indicator Troubleshooting Table
- Scheduled Maintenance
- Authorized Repair Service
- Frequently Asked Questions

This section presents information about the AED diagnostics self-tests, maintenance, and service indications.

Self-Tests

The AED has a comprehensive self-test system that automatically tests the electronics, battery, pads, and high voltage circuitry. Self-tests are also activated every time you open and close the AED lid.

When performing the self-tests, the AED completes the following steps automatically:

1. Turns itself ON, and the Status Indicator changes to RED.
2. Performs the self-test.
3. If successful, the Status Indicator reverts to GREEN.
4. Turns itself OFF if the lid is closed.

There are three types of automatic self-tests:

- The Daily Self-test checks the battery, pads, and the electronic components.
- The Weekly Self-test completes a partial charge of the high voltage electronics current in addition to the items tested in the Daily Self-test.

- During the Monthly Self-test, the high voltage electronics are charged to full energy.

Self-tests will be initiated upon opening the lid and again upon closing the lid. If the self-test detects an error, the Status Indicator will remain RED. Upon closing the lid, an audible alert will be issued. The Diagnostic Panel under the lid will indicate the source of the problem according to the Indicator Troubleshooting Guide Table on the next page.

Indicator Troubleshooting Table

The following is a troubleshooting table for the AED indicators.

Table 11: Indicator Troubleshooting Table

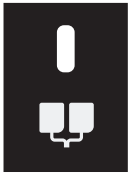
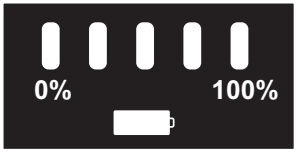
View	Symptom	Solution
	Red SERVICE indicator (LED) is lit.	Maintenance by authorized service personnel is required. Call Cardiac Science Customer Service (see page 4) or your local Cardiac Science distributor.
	Red Pads indicator (LED) is lit.	Connect the pads or replace with a new pair.
	The last battery indicator (LED) is red.	The battery is low. Replace with a new battery.

Table 11: Indicator Troubleshooting Table (continued)

View	Symptom	Solution
	STATUS INDICATOR is RED, and no other indicators on the diagnostic panel are lit.	The battery power is completely depleted. Replace with a new battery. If STATUS INDICATOR remains RED call Cardiac Science Customer Service or your local Cardiac Science distributor.

CAUTION: Temperature Extremes.

Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The RescueReady daily self-test verifies the impact of extreme environmental conditions on the AED. If the daily self-test determines environmental conditions outside of the AED's operating parameters, a "SERVICE REQUIRED" alert will be issued to prompt the user to move the AED to environmental conditions within the acceptable operating parameters at once. See Technical Data on page 7-1

Scheduled Maintenance

Perform the following tests per the schedule indicated:

Daily Maintenance

Check the Status Indicator to ensure that it is GREEN. When the indicator is GREEN, the AED is ready for a rescue. If the indicator is RED, refer to the Troubleshooting Table in this chapter.

Monthly Maintenance

Perform the following procedure each month (28 days)

1. Open the AED lid.
2. Wait for the AED to indicate status: Observe the change of the STATUS INDICATOR to RED. After approximately 5 seconds, verify that the STATUS INDICATOR returns to GREEN.
3. Check the expiration date on the electrodes.
4. Listen for the voice prompts.

5 Close the lid and observe the change of the STATUS INDICATOR to RED. After approximately 5 seconds, verify that the STATUS INDICATOR returns to GREEN.

Annual Maintenance

Perform the following tests annually to confirm that the diagnostics are functioning properly and to verify the integrity of the case.

Check the Integrity of the Pads and Circuitry:

1 Open the AED lid.
2 Remove the pads.
3 Close the lid.
4 Confirm that the STATUS INDICATOR turns RED.
5 Open the lid and confirm that the Pad indicator is lit.
6 Reconnect the pads and close the lid.
7 Make sure the expiration date is visible through the clear window of the lid.
8 Check to make sure that the STATUS INDICATOR is GREEN. If the pads are not installed properly, the PAD indicator will illuminate; call Customer Service for assistance.
9 Open the lid and confirm that no diagnostic indicators are lit.
10 Check the expiration date of the pads; if expired, replace them.
11 Check the pads packaging integrity.
12 Close the lid

Check the Integrity of the Service Indicator (LED) and Circuitry:

1 Immediately after opening the AED lid, press and hold the Shock button and confirm that the Service LED is lit.
2 Release the Shock/Continue button.
3 Close the lid.
4 Verify that the STATUS INDICATOR remains RED.
5 Open the lid and confirm that no diagnostic indicators are lit.
6 Close the lid.

7 Verify that the STATUS INDICATOR turns GREEN.

Check the Integrity of the Case:

Examine the molded case of the AED for any visible signs of stress. If the case shows signs of stress, contact Cardiac Science Customer Service (See Contact Information on page 1-1) or contact your local Cardiac Science distributor.

CAUTION: Case Cleaning Solutions.

When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or a glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

Authorized Repair Service

The AED has no user-serviceable internal components. Try to resolve any maintenance issues with the AED by using the Troubleshooting Table presented in this chapter. If you are unable to resolve the problem, contact Cardiac Science Customer Service (See Contact Information on page 1-1) or contact your local Cardiac Science distributor.

WARNING: Shock Hazard.

Do not disassemble the AED. Failure to observe this warning can result in personal injury or death. Refer maintenance issues to Cardiac Science authorized service personnel.

Note: The warranty will be void upon unauthorized disassembly or service of the AED.

Frequently Asked Questions

Q: Can I give CPR while the AED is analyzing?

A: No. As with all AEDs, the operator should stop CPR compressions during the analysis phase.

Q: Can I transport the victim while the AED is analyzing?

A. No. Vehicle motion may cause noise artifacts that could interfere with proper cardiac rhythm analysis. Stop the vehicle when cardiac rhythm analysis is necessary.

Q: Do I need to prepare the chest prior to pad application?

A: Special preparation is not usually necessary. The chest should be as clean, dry, and as oil free as possible. Follow your Medical Director's instruction.

Q: What happens if the battery is low when I begin a rescue?

A: When the battery indicator is red, the AED issues a "Battery Low" prompt once; however, the AED is still capable of delivering approximately 9 more defibrillation shocks.

When the AED is not capable of delivering any more shocks, it "beeps" once every 30 seconds.

To continue the rescue attempt, leave the lid open and replace the battery. When the battery replacement takes longer than 60 seconds, the first rescue is terminated and the AED will begin to record the events from then on as a separate rescue.

Q: How do I set the AED internal clock?

A: Set the clock by using the RescueLink Software Program and a PC. See Setting the AED Internal Clock in Chapter 3.

Q: What happens if I close the lid in the middle of a rescue attempt?

A: If you close the lid during a rescue, you must re-open the lid within 15 seconds to continue the rescue. You will hear the prompt, "Open lid to Continue Rescue." If the lid remains closed for more than 15 seconds, a new rescue will initiate when the lid is reopened.

Note: If the lid is closed during a rescue while the pads are connected to the patient, the STATUS INDICATOR remains GREEN. When the lid is reopened, however, the STATUS INDICATOR will turn RED and then back to GREEN. The rescue may be continued.

Q: My AED is sounding an audible alert. Why? How do I stop it?

A: The audible alert indicates that the self-test detected a need for maintenance or corrective action. Determine the maintenance required by using the Troubleshooting Table in this chapter. Opening and closing the lid may turn OFF the audible alert until the next self-test. However, the STATUS INDICATOR will remain RED.

Q: The AED did not sound an audible alert when I removed the pads and closed the lid. Why?

Note: Ensure the battery is installed. The AED will never beep while battery is removed.

A: The lid-closed pad self-test only activates the STATUS INDICATOR. The AED allows time for replacement of the pads—as removing pads is a normal procedure after a rescue—or a battery during the post rescue procedure. However, if both the pads and battery are removed and replaced, an audible maintenance indicator will be triggered after the next daily self-test.

Q: What if I have to perform a rescue in an isolated area and at subzero temperatures?

A: When travel to a rescue involves exposing the AED to extremely cold temperatures for an extended period of time, keep the pads and the battery warm.

7 Technical Data

What's in this chapter

- Parameters
- Star Biphasic Waveform

This section lists the AED parameters.

Parameters

Table 12: Parameters

Parameter	Detail
Operation	Semi-Automatic (shock advisory) Automatic
Audible Alerts	Voice Prompt Maintenance Alert
Visible Indicators	Status Indicator Battery Status Indicator Service Indicator Pads Indicator Text Display
Rescue Data Storage	Internal with 60 minutes ECG data with event annotation
Dimensions	Height: 8 cm (3.3 in) Width: 27 cm (10.6 in) Depth: 31 cm (12.4 in)
Weight (Batteries and Pads)	9390: 3.10 kg (6.6 lb)

Table 12: Parameters (continued)

Parameter	Detail
Environmental Operation and Standby Conditions	Temperature: 0°C to 50°C (32°F to 122°F) Humidity: 5% to 95% (non-condensing) Pressure: 57kPa (+15,000ft) to 103kPa (-500ft)
Shipment and Transport environmental Conditions (for up to 1 week)	Temperature: -30°C to 65°C (-22°F to 149°F) Humidity: 5% to 95% (non-condensing) Pressure: 57kPa (+15,000ft) to 103kPa (-500ft)
Pads	Self-adhesive, disposable defibrillation pads Minimum combined surface area: 228cm^2 Extended length of lead wire: 1.3m
9146 Lithium Battery Specifications (p/n: 9146-001)	Output voltage: 12VDC (max) Batteries are non-rechargeable Lithium contents: 9.2g (max) Check local regulations for disposal information Full Operational Replacement Guarantee (from date of installation): 4 Years Estimated Shelf Life (from date of manufacture): 5 Years Typical Shocks: up to 290 shocks **Note:** The battery operating life depends on the type of battery, actual usage and environmental factors.
Batteries and Capacitor Charge Times	A new battery typically takes 10 seconds to charge the AED to maximum energy. A battery with reduced capacity causes the red LED light to initially turn ON and typically takes 13 seconds to charge a fully discharged AED to maximum energy.

Table 12: Parameters (continued)

Parameter	Detail
AED Self test Sequence	Daily: Battery, pads, internal electronics, Shock/ Continue or button, and software (no charge). Weekly: Battery, pads, internal electronics, Shock/ Continue, and software (partial charge). Monthly (every 28 days): Battery under load, pads, internal electronics, full-energy charge cycle, Shock/Continue button, and software (full charge). Open Lid (when lid is opened): Battery, pads, internal electronics, Shock/Continue button, and software. Close Lid (when lid is closed): Battery, pads, internal electronics, Shock/Continue button, and software.

Table 12: Parameters (continued)

Parameter	Detail
Safety and Performance	Model 9390 The AED has been designed and manufactured to conform to the highest standards of safety and performance including electromagnetic compatibility (EMC). The 9390 and pads conform to the applicable requirements of the following: CE CE Marked by BSI 0086 per the Medical Device Directive 93/42/EEC ETL Classified by ETL Semko with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, EN60601-1 and EN60601-2-4. Conforms to UL Standard UL60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.

Table 12: Parameters (continued)

Parameter	Detail
	Electrical, Construction, Safety and Performance IEC 60601-1 (1998), Amendments 1 (1991) & 2 (1995) IEC 60601-2-4 (2002) ANSI/AAMI DF-39 (1993) Electromagnetic Compatibility (EMC) IEC 60601-1-2 (2001) IEC 60601-2-4 Section 36 ANSI/AAMI DF-39 (1993) Section 3.3.21
Emissions	EM: EN 55011/CISPR 11, Group 1, Class B Magnetic: ANSI/AAMI DF39, <0.5mT on surface, except for within 5cm of the lid magnet and the speaker
Immunity	EM • EC 61000-4-3, Level X, (20V/m) • EC 60601-2-4, Section 36.202.3 (20V/m) • AAMI DF39, Section 3.3.21.2.1 Magnetic • IEC 61000-4-8 (2001) • IEC 60601-2-4 (2002), Section 36.202.8 • AAMI DF39, Section 3.3.21.2.3 80A/m, 47.5Hz – 1,320Hz ESD • IEC 61000-4-2, Level 3 • IEC 60601-2-4 (2002), Section 36.202.2 • 6KV contact discharge, 8KV air gap discharge

Table 12: Parameters (continued)

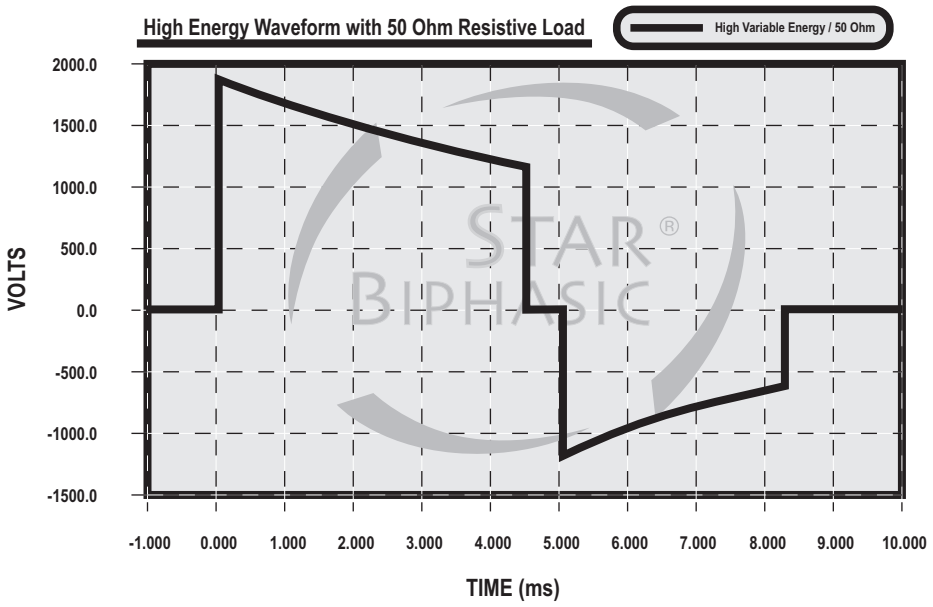
Parameter	Detail
Environmental Conditions	Free Fall Drop: IEC 60068-2-32 (1975) AM 2 (1990), 1 meter Bump: IEC 60068-2-29 (1987), 40g and 6000 bumps Vibration (Random): IEC 60068-2-64 (1993): 10Hz – 2KHz, 0.005 – 0.0012 g^2/Hz Vibration (Sine): IEC 60068-2-6 (1995): 10Hz – 60Hz, 0.15 mm and 60Hz – 150Hz, 2g Enclosure Protection: IEC 60529 (2001), IP24
Shipping and Transportation Conditions	ISTA Procedure 2A
RHYTHMx ECG Analysis Performance	The AED RHYTHMx ECG Analysis system analyzes the patient's ECG and advises you when the AED detects a shockable or non-shockable rhythm. This system makes it possible for a person, with no training in the interpretation of ECG rhythms, to offer defibrillation therapy to victims of sudden cardiac arrest.

Table 12: Parameters (continued)

Parameter	Detail
Cardiac Rhythms Used to Test the Rhythm Recognition Detection System for Powerheart G3 AEDs	Shockable Rhythm* – VF: Meets AAMI DF 39 requirement and AHA recommendation of Sensitivity of >90% (*Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms and Enhancing Safety, AHA AED Task Force and approved by the AHA Science Advisory and Coordinating Committee. Circulation, 1997(95), pp 1677-1682) Shockable Rhythm – VT: Meets AAMI DF 39 requirement and AHA recommendation of Sensitivity of >75% Non-shockable Rhythm – NSR: Meets AAMI DF 39 requirement (>95%) and AHA recommendation (>99%) of Specificity Non-shockable – Asystole: Meets AAMI DF 39 requirement and AHA recommendation of Specificity of >95% Non-shockable: Meets AAMI DF 39 requirement and AHA recommendation of Specificity – all other rhythms of >95% For detailed information contact Cardiac Science for white papers: • P/N 112-2013-001 (Pediatric Defibrillation Instructions) • P/N 110-0033-001 (RHYTHMx White Paper) • P/N 400781 (STAR Biphasic White Paper)

Star Biphasic Waveform

The waveform generated by the AED is a Biphasic Truncated Exponential waveform that is compliant with ANSI/AAMI DF2 and DF39. The following is a graph of the waveform voltage as a function of time when the AED is connected to a 50 Ohm resistive load.



The Biphasic Truncated Exponential (BTE) waveform uses variable energy. The actual energy delivered will vary with the patient's impedance and the device will deliver a shock when impedance is between 25-180 Ohms. Energy will be delivered at three different levels referred to as ultra-low variable energy, low variable energy, and high variable energy as shown in the waveform tables below.

Table 13: Ultra-low Energy Powerheart G3 Waveform (all values are typical)

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	Voltage (Volts)	Duration (MS)	Voltage (Volts)	Duration (MS)	Energy (Joules)
25	1390	3.3	730	3.2	145-195
50	1420	4.5	915	3.2	130-175
75	1430	5.8	980	3.2	120-160
100	1435	7.0	1020	3.2	110-150
125	1440	8.3	1040	3.2	105-140

Table 14: Low Variable Energy Powerheart G3 Waveform (all values are typical)

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	Voltage (Volts)	Duration (MS)	Voltage (Volts)	Duration (MS)	Energy (Joules)
25	1570	3.3	825	3.2	200-250
50	1600	4.5	1030	3.2	170-210
75	1610	5.8	1105	3.2	120-160
100	1615	7.0	1150	3.2	150-180
125	1620	8.3	1170	3.2	140-170

Table 15: High Variable Energy Powerheart G3 Waveform (all values are typical)

	Phase 1		Phase 2		
Patient's Impedance (Ohms)	Voltage (Volts)	Duration (MS)	Voltage (Volts)	Duration (MS)	Energy (Joules)
25	1885	3.3	990	3.2	265-360
50	1920	4.5	1240	3.2	235-320
75	1930	5.8	1325	3.2	215-295
100	1940	7.0	1380	3.2	200-270
125	1945	8.3	1405	3.2	190-260